

REMARKS

Applicant respectfully requests reconsideration of this application in view of the amendments and remarks made herein.

Claims 1, 3, 7, 10-17, 21-23, 26, and 28-37 are currently pending.

Claims 1, 3, 7, 10-14, 16-17, 21-23, 26, and 28-37 have been amended, as discussed in detail herein. No new matter has been added by these claim amendments.

New claims 28-37 have been added. Applicant respectfully submits that the present new claims are drawn to elected Groups II and VI and are supported by the original disclosure of this application. As such, no new matter has been added by these new claims.

Claims 2, 4-6, 8-9, 18-20, 24, 25, and 27 have been withdrawn from consideration by applicant without prejudice to the prosecution of the subject matter of these claims in other applications since these claims are drawn to separately patentable inventions as determined by the Examiner in the Restriction Requirement of March 11, 2003 and the Office Action of December 24, 2003. Applicant reserves the right to prosecute the subject matter of these withdrawn claims in one or more divisional and/or continuation applications.

Applicant amended the specification to correct typographical errors in the original application as filed. None of these amendments add any new matter to this application.

Election/Restrictions

In response to the Restriction Requirement of March 11, 2003 and the Examiner's comments in the Office Action of December 24, 2003, applicant elects to prosecute the inventions of Groups II and VI in this application and reserves the right to Petition the Commissioner under 37 C.F.R. § 1.144. Claims 2, 4-6, 8-9, 18-20, 24-25, and 27 are withdrawn from consideration in this application without prejudice to the prosecution of the subject matter of these claims in other applications.

Claim Objections

1. Dependent Claim Format: Claim 7

The Examiner objected to dependent claim 7 as being in improper dependent format for not limiting the subject matter of a previous claim. Applicant acknowledges the Examiner's position that independent claim 1 drawn to a coding sequence of a maize ribosome inactivating protein broadly covers a coding sequence such as SEQ. ID No.:2 and a coding sequence which is homologous to SEQ. ID No.:2.

In response, applicant has amended claim 7 such that the coding sequence "consists of" the sequence identified in SEQ. ID No.:2 or homologues thereof. Applicant respectfully requests that the Examiner withdraw this objection to claim 7.

2. Dependent Claims Drawn to Elected Claims: Claims 10-17 and 21-22

The Examiner objected to the format of claims 10-17 and 21-22 as dependent from nonelected claims.

Applicant has amended claims 10-14, 16-17, and 21-22 to depend from elected claims and respectfully reserves the right to prosecute all nonelected subject matter in separate applications. The amendment to claim 14 adjusted the dependency of claim 15 to depend ultimately from elected claim 1. As such, applicant respectfully requests that these objections to claims 10-17 and 21-22 be withdrawn.

3. Claims Drawn to Elected Sequence Identifiers: Claims 10-13

The Examiner objected to the format of claims 10-13 as drawn to cover sequence identifiers of nonelected inventions.

In response, applicant has amended claims 10-13 to remove reference to SEQ. ID Nos.:1, 3, and 4. Applicant respectfully reserves the right to prosecute the subject matter of all nonelected inventions. Withdrawal of the objections to claims 10-13 is respectfully requested.

4. Multiple Dependent Claim Format: Claims 10-17 and 21-22

The Examiner objected to the multiple dependent format of claims 10-17 and 21-22, which depended from other multiple dependant claims.

Applicant has amended the claims to remove the multiple dependence on multiple dependent claims, such that claims 10-13 and 21-22 now depend individually from claim 7; claims 14 and 17 now depend individually from claim 1; claim 15 now depends from claim 14; and claim 16 multiply depends from claim 14 or 15. None of these claims now depend from a multiple dependent claim. In addition, since applicant amended these claims to depend from the elected claim of the lowest relevant numerical value, applicant has not narrowed the breadth of the claim scope of any of these claims by way of these amendments. Applicant respectfully requests that these objections be withdrawn by the Examiner.

Claim Rejections Under 35 U.S.C. § 112

1. Section 112, First Paragraph

a. Invention Is Adequately Described in the Specification

The Examiner rejected claims 1, 3, 7, 10-17, 21-23, and 26 under 35 U.S.C. § 112, first paragraph, as not supported by the scope of the description of the invention in the specification. According to the Examiner, the specification does not provide a sufficient written description of ribosome inactivating proteins other than type 3 ribosome inactivating proteins obtained from maize, or the nucleic acid sequences encoding them, in order to convey to a person of ordinary skill in the art that the inventors had possession of the claimed invention.

Applicant amended claims 1, 3, 23 and 26 to be drawn to the genus of maize type 3 ribosome inactivating proteins, and homologues thereof, as supported by the disclosure of the specification. Applicant's amendment of this element of the claims does not narrow the scope of the claimed invention, since, as stated in the specification at paragraph [0015], "[m]aize RIP, which is found in the endosperm of maize (*Zea mays*) seeds, is a Type 3 RIP."

The Examiner stated that the specification does not describe the structure of sequences characterized as being evolutionarily related (homologous) to SEQ. ID. No.: 2, or having 70-90% homology to SEQ. ID No.:2 that encode functional proteins.

First, applicant respectfully traverses this rejection as inapposite to claims 1, 3, 14-17 and 21-23, and 26, which do not contain the claim elements of SEQ. ID No.:2 or homologues thereof.

Second, a person of skill in the art at the time this application was filed would have understood the functional definition of “homology” to be a percent similarity with an identified sequence after hybridizing under high stringency conditions with complement of the identified sequence wherein the homologue has catalytic activity. As such, applicant amended claims 10-13 to define a homologous coding sequence having a percent homology along with hybridization conditions and a described functionality corresponding to the maize type 3 ribosome inactivating protein, which is fully described in the specification as having certain enzymatic functionality. In addition, applicant’s amendment to claims 10-13 to insert this functional definition of homology does not narrow the scope of claims 10-13 because the meaning of “homology” was implicit in the claims as filed.

Applicant respectfully submits that claims 1, 3, 7, 10-17, 21-23, and 26 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

b. Claims Are Enabled to Person of Skill in the Art to Practice Invention

The Examiner rejected claims 1, 3, 7, 10-17, 21-23, and 26 under 35 U.S.C. § 112, first paragraph, as not enabled for a method of producing a transgenic of any species of plant having any unspecified type of homology to SEQ. ID No.: 2. The Examiner admits that the specification is enabling for the broad genus of solanaceous plants.

Applicant has amended claim 1 to be drawn to a method of producing a transgenic solanaceous plant. No amendment of claims 23 or 26 is required since neither is drawn to a method of producing a transgenic plant.

In response to the Examiner’s comments regarding a lack of enablement for a method of producing a transgenic plant having a chimeric gene comprising a coding sequence having any unspecified type of homology to SEQ. ID No.:2, or having 70%-90% homology to SEQ. ID

No.:2, or encoding any unidentified maize ribosome inactivating protein or part thereof, applicant amended claims 10-13 to define a homologous coding sequence having a percent homology along with hybridization conditions and described functionality corresponding to the maize type 3 ribosome inactivating protein, which is fully described in the specification as having certain enzymatic functionality, and amended claims 1, 3, 23, and 26 to be drawn to the genus of maize type 3 ribosome inactivating proteins and homologues thereof. As such, the Examiner's concerns about the specificity of the type of ribosome inactivating protein and homologues corresponding to the structural and functional characteristics of the coding sequence have been addressed.

Applicant respectfully requests that the Examiner withdraw these rejections of claims 1, 3, 7, 10-17, 21-23, and 26 under 35 U.S.C. § 112, first paragraph.

2. Section 112, Second Paragraph

The Examiner rejected claims 1, 3, 7, 10-17, 21-23, and 26 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claims the subject matter that applicant regards as the invention. Specifically, the Examiner objected to the following terms as indefinite: "target site" in claims 1, 21-23, and 26, "which promoter is induced at and/or adjacent to a target site" in claims 1, 21-23, and 26, "% homology with" in claims 11-13, "has at least 70% with" in claim 10, "selected from the group comprising" in claim 16, "plant cell transformed with a chimaeric gene according to the method of any one of claims 1-20" in claim 22, "a DNA isolate of a chimaeric gene" in claim 23, and "biologically functional expression vehicle" in claim 26.

a. Claims 1, 21-23, and 26

According to the Examiner, the phrases "target site" and "which promoter is induced at and/or adjacent to a target site" in claims 1, 21-23, and 26 are indefinite. In particular, the Examiner states that "target site" could be interpreted as a location in a plant body, in a plant cell (nucleous), or in a specific intracellular location.

It is clear from the specification that “target site” as claimed refers to a location in a plant body. Many examples are provided throughout the specification, for instance paragraphs [0012], [0033], and [0037] – [0040] state in pertinent part (emphasis added):

[0012] Other applications of plant cell death systems can be envisioned. For example the *target site may be specific parts of the flower*, thereby altering the morphology of the flower. Alternatively the *target site may be lateral roots, thorns or stinging hairs*. *Abscission of leaf or fruit might be achieved by the targeting the abscission zone of the leaf or the fruit*. Facilitating the release of seeds from plants, by *targeting the funicle* might be achievable. By targeting other organs such as trichomes, which trichomes are typically glandular, the production of chemical substances by the trichomes can be cessated or prevented. Another application might be the *inducible abscission of roots, leaves, flowers, or fruit* at the end of the growing season.

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[0033] In accordance with a first embodiment of the present invention, the *target site may be a nematode feeding site*. When it is the case that the target site is a nematode feeding site, the promoter selected is one which is induced at and/or adjacent to the nematode feeding site. Such a promoter is preferably induced upon nematode infection of the plant.

* * * * *

[0037] In accordance with a second aspect of the present invention, instead of nematode resistance the method is directed to effecting male sterility in plants. For example, the *target site may be one or more of a plant's pollen, anther or tapetum*. When it is the case that the target site is tapetum for example, the promoter selected is one that is induced in and/or adjacent to the tapetum. An example of a suitable tapetum promoter is the tobacco TA29 promoter as disclosed in Mariani et al (1990). Anther specific promoters are disclosed in Twell et al (1991).

[0038] In accordance with a third aspect of the present invention, the method is directed to effecting female sterility in plants. For example, the *target site may be the ovule of the plant*. That is to say, the promoter selected is one that is induced in and/or adjacent to the ovule. An example of a suitable promoter is the AGL15 promoter as disclosed in Perry et al, 1996.

[0039] According to a fourth aspect of the present invention, the morphology of the flower of a plant is manipulated. For example, the *target site may be specific parts of the flower, the aim being that when these specific parts of the flower do not develop the morphology of the flower is changed*. In that instance, the promoter selected is one that is induced in and/or adjacent to the *sepal, carpel, petal, and/or stamen*. Examples of suitable promoters are those found in the *agamous*, *apetala3*, *globosa*, *pistillata* and *deficiens* genes (Sieburth and Meyerowitz, 1997; Samach et al, 1997 and references therein).

[0040] In accordance with a fifth aspect of the present invention, the method is used to assist in or promote leaf and/or fruit abscission in plants. For example, *the target site may be the abscission zone of the leaf and/or the fruit*. Thus, the promoter selected is one that is induced in and/or adjacent to such an abscission zone.

It is clear from these examples that the use of the phrase “target site” in claims 1, 21-23, and 26 is not indefinite.

With this clarification of the meaning of the phrase “target site,” the Examiner’s concerns about the phrase “which promoter is induced at and/or adjacent to a target site” and how the promoter “adjacent to” the target site are also addressed. The above paragraphs provide specific examples of how a promoter can be induced at and/or adjacent to a particular site such that the ribosome inactivating protein causes cytotoxicity at and/or adjacent to the target site.

Applicant respectfully requests that the Examiner withdraw these rejections of claims 1, 21-23, and 26 under 35 U.S.C. § 112, second paragraph.

b. Claims 10-13

According to the Examiner, the phrase “has at least 70% with” in claim 10 and the phrase “% homology with” in claims 11-13 are indefinite.

Applicant addressed the Examiner’s concerns regarding structural and functional homology by amending claims 10-13 to clarify that the homologous coding sequence has a percent homology with an identified sequence after hybridizing under high stringency conditions with a complement of the identified sequence and has a functionality corresponding to maize type 3 ribosome inactivating protein. In addition, applicant amended claim 10 to correct the inadvertent omission of the word “homology” after “70%” in claim 10. As such, applicant respectfully requests that the Examiner withdraw these rejections of claims 10-13 under 35 U.S.C. § 112, second paragraph.

c. Claim 16

The Examiner stated that the phrase “selected from the group comprising” in claim 16 is indefinite because the term “comprising” is an open ended term that does not define the metes

and bounds of a closed group. In response, applicant amended claim 16 to replace “comprising” with “consists of,” as recommended by the Examiner, in order to correct the format of this Markush group. It is respectfully requested that this rejection under 35 U.S.C. § 112, second paragraph, be withdrawn by the Examiner.

d. Claim 22

The Examiner stated that “plant cell transformed with a chimaeric gene according to the method of any one of claims 1-20” in claim 22 was indefinite due to a lack of antecedent basis for the phrase “plant cell.”

In response, applicant amended claim 22 to be drawn to “a cell of the plant” transformed with a chimeric gene according to the method of claim 1 in order to address the Examiner’s concern. Applicant respectfully requests withdrawal of this rejection of claim 22 under 35 U.S.C. § 112, second paragraph, by the Examiner.

In addition, applicant also deleted a substantial portion of claim 22 (and claim 21) for clarity because each of the deleted elements are already present in claim 1. As such, these amendments have not narrowed the scope of claims 21 or 22 as originally filed.

e. Claim 23

The Examiner stated that “a DNA isolate of a chimaeric gene” in claim 23 is indefinite because of the term “isolate.” As such, applicant has amended claim 23 to remove the term “isolate” and replaced it with the broader term “construct.” Applicant respectfully requests that the Examiner withdraw this rejection of claim 23 under 35 U.S.C. § 112, second paragraph.

f. Claim 26

The Examiner stated that the phrase “biologically functional expression vehicle” in claim 26 was indefinite because it was unclear what was meant by the term “vehicle.” In response, applicant has broadened claim 26 by replacing “biologically functional expression vehicle” with the term “vector” in order to address the Examiner’s concerns. As such, it is respectfully

requested that the rejection of this claim under 35 U.S.C. § 112, second paragraph, be withdrawn by the Examiner.

Claims Are Not Anticipated by Maddaloni *et al.*

The Examiner rejected claims 1, 7, 10-17, 21-23, and 26 under 35 U.S.C. § 102(b) as being anticipated by Maddaloni *et al.* According to the Examiner, Maddaloni *et al.* teach a method of producing a transgenic tobacco plant transformed with a chimeric gene comprising a potato wound-inducible *wun 1* promoter operably linked to a coding sequence encoding a maize ribosome inactivating protein.

The method disclosed in Maddaloni *et al.* directs the ribosome inactivating protein against an invading external eukaryote (*Rhizoctonia solani*). In contrast to the use of a constitutive promoter used by Maddaloni *et al.*, the present invention involves a target tissue specific inducible promoter linked to a coding sequence, the expression of which causes plant cytotoxicity of the host plant at a target site when the promoter is induced at and/or adjacent to the target site. The use of the target tissue specific promoter allows for localized expression of the maize type 3 ribosome inactivating protein at and/or adjacent to specific target sites according to the present invention.

Maddaloni *et al.* do not disclose, teach, or suggest the use of a target tissue specific inducible promoter for specific localized expression at and/or adjacent to a target site.

Thus, applicant respectfully submits that Maddaloni *et al.* do not disclose each and every element of the present invention and accordingly request withdrawal of the rejection of claims 1, 7, 10-17, 21-23, and 26 as anticipated by Maddaloni *et al.*

Claims Are Not Obvious Over Cited Art

The Examiner rejected claims 1, 3, and 14-17 under 35 U.S.C. 103(a) as being unpatentable as obvious over Maddaloni *et al.* in view of Hey *et al.* and Boston *et al.* The Examiner admits that Maddaloni *et al.* do not teach recombinant mature ribosome inactivating protein comprising an α domain and a β domain arranged contiguously, or the use of a pea *rbcs* E9 terminator, a *nos* terminator, or a CaMV 35S terminator. However, according to the

Examiner, Hey *et al.* teach a biologically active recombinant mature maize ribosome inactivating protein comprising an α domain and a β domain arranged contiguously, and Boston *et al.* teach the use of a nos terminator in a plant expression construct design to express a sequence encoding a maize ribosome activating protein.

As discussed above, Maddaloni *et al.* do not disclose, teach, or suggest the use of a target tissue specific inducible promoter to achieve specific localized expression of maize type 3 ribosome inactivating protein at and/or adjacent to a target site in the host plant. In fact, Maddaloni *et al.* teach away from the present invention because Maddaloni *et al.* teach the use of a constitutive promoter to achieve generalized expression to promote an increased tolerance against infection from a soil-borne fungal pathogen by directing ribosome inactivating protein activity toward the invading pathogen.

Further, Maddaloni *et al.* do not teach localized promoter expression to induce cell death at and/or adjacent to target sites tailored, for example, to improve nematode resistance or effecting pollen sterility. Instead, concerned about cell death of the host plant, it is suggested by Maddaloni *et al.* that the use of high catalytic activity of ribosome inactivating proteins might not necessarily be the most appropriate strategy.

Hey *et al.* and Boson *et al.* do not make up for the deficiencies of Maddaloni *et al.* as neither Hey *et al.* nor Boson *et al.* disclose, teach, or suggest the use of a target tissue specific promoter to achieve specific localized expression at and/or adjacent to a target site.

Since none of the cited references, alone or in combination, disclose, teach, or suggest the subject matter of claims 1, 3, and 14-17, applicant respectfully requests that the Examiner withdraw the rejection of these claims as obvious over Maddaloni *et al.* in view of Hey *et al.* and Boston *et al.*


CONCLUSION

Applicants respectfully submit that all pending claims 1, 3, 7, 10-17, 21-23, 26, and 28-37 are presently in condition for allowance. Prompt and favorable reconsideration and allowance of all pending claims is respectfully requested.

The Commissioner is authorized to charge any fees relevant to this filing to Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned to discuss any matter in this application.

Respectfully submitted,
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